### **EXHIBIT 1**

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DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop C2-21-16 Baltimore, Maryland 21244-1850



#### Center for Clinical Standards and Quality

**Ref: QSO-22-22-Hospitals** 

**DATE:** July 11, 2022

**TO:** State Survey Agency Directors

**FROM:** Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations

Group (SOG)

**SUBJECT:** Reinforcement of EMTALA Obligations specific to Patients who are

Pregnant or are Experiencing Pregnancy Loss (QSO-21-22-Hospitals-

UPDATED JULY 2022)

NOTE: This memorandum is being issued to remind hospitals of their existing obligation to comply with EMTALA and does not contain new policy.

#### **Memorandum Summary**

- The Emergency Medical Treatment and Labor Act (EMTALA) provides rights to any individual who comes to a hospital emergency department and requests examination or treatment. In particular, if such a request is made, hospitals must provide an appropriate medical screening examination to determine whether an emergency medical condition exists or whether the person is in labor. If an emergency medical condition is found to exist, the hospital must provide available stabilizing treatment or an appropriate transfer to another hospital that has the capabilities to provide stabilizing treatment. The EMTALA statute requires that all patients receive an appropriate medical screening examination, stabilizing treatment, and transfer, if necessary, irrespective of any state laws or mandates that apply to specific procedures.
- The determination of an emergency medical condition is the responsibility of the examining physician or other qualified medical personnel. An emergency medical condition may include a condition that is likely or certain to become emergent without stabilizing treatment. Emergency medical conditions involving pregnant patients may include, but are not limited to, ectopic pregnancy, complications of pregnancy loss, or emergent hypertensive disorders, such as preeclampsia with severe features.
- Hospitals should ensure all staff who may come into contact with a patient seeking examination or treatment of a medical condition are aware of the hospital's obligation under EMTALA.
- A physician's professional and legal duty to provide stabilizing medical treatment to a patient who presents under EMTALA to the emergency department and is found to have an emergency medical condition preempts any directly conflicting state law or mandate that might otherwise prohibit or prevent such treatment.
- If a physician believes that a pregnant patient presenting at an emergency department is experiencing an emergency medical condition as defined by EMTALA, and that abortion is the stabilizing treatment necessary to resolve that condition, the physician must provide that treatment. When a state law prohibits abortion and does not include an exception for the life of the pregnant person or draws the exception more narrowly than EMTALA's emergency medical condition definition that state law is preempted.

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The purpose of this memorandum is to restate existing guidance for hospital staff and physicians regarding their obligations under the Emergency Medical Treatment and Labor Act (EMTALA), in light of new state laws prohibiting or restricting access to abortion.

The EMTALA statute is codified at section 1867 of the Social Security Act, 42 U.S.C. § 1395dd. Hospitals and physicians generally have three obligations under EMTALA. The first is commonly referred to as the *screening requirement*, and applies to any individual who comes to the emergency department for whom a request is made for examination or treatment of a medical condition, including people in labor or those with an emergency condition such as an ectopic pregnancy. Such an individual is entitled to have a medical screening examination to determine whether an emergency medical condition (EMC) exists. The second obligation is commonly referred to as the *stabilization requirement*, which applies to any individual who comes to the hospital whom the hospital determines has an emergency medical condition. Such an individual is entitled to stabilizing treatment within the capability of the hospital. The third obligation flows from the second, and also applies to any individual in a hospital with an emergency medical condition. This obligation is sometimes known as the transfer requirement, which restricts the ability of the hospital to transfer that individual to another hospital unless the individual is stabilized. If the individual is not stabilized, they may only be transferred if the individual requests the transfer or if the medical benefits of the transfer outweigh the risks (e.g., the hospital does not have the capability to stabilize the condition).

While a patient may request a transfer for any reason, a hospital is restricted by EMTALA to transfer patients only after a physician certifies that the medical benefits of the transfer outweigh the risks. The EMTALA regulation at 42 CFR §489.24 clarifies that the screening requirement applies to any individual who presents to an area of the hospital that meets the definition of a "dedicated emergency department" and makes a request for a medical screening examination. The regulation defines dedicated emergency department as the area of the hospital that met any one of three tests: that it is licensed by the state as an emergency department; that it holds itself out to the public as providing emergency care; or that during the preceding calendar year, at least one-third of its outpatient visits were for the treatment of emergency medical conditions. Based on this definition, it is likely that the labor and delivery unit of a hospital could meet the definition of dedicated emergency department.

#### **Medicare Conditions of Participation**

Hospitals are also bound by the Medicare conditions of participation (CoPs) to provide appropriate care to inpatients (42 C.F.R. 482.1 through 482.58). In particular, four CoPs are potentially applicable when a hospital provides treatment for an admitted patient. For example, the governing body must ensure that the medical staff as a group is accountable to the governing body for the quality of care provided to patients (42 C.F.R. 482.12(a)(5) and 42 C.F.R. 482.22). Further, the discharge planning CoP (42 C.F.R. 482.43), which requires that hospitals have a discharge planning process, applies to all patients. Finally, the hospital governing body must ensure that the hospital has an organization-wide quality assessment and performance improvement program to evaluate the provision of patient care (42 C.F. R. 482.21). These CoPs are intended to protect patient health and safety, and to ensure that high quality medical care is provided to all patients. Failure to meet these CoPs could result in a finding of noncompliance at

<sup>&</sup>lt;sup>1</sup> Appendix V of the CMS State Operations Manual-: <a href="https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap">https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap</a> V emerg.pdf

Case 5:22-cv-00185-H Document 1-1 Filed 07/14/22 Page 4 of 7 PageID 24 the condition level for the hospital and lead to termination of the hospital's Medicare provider agreement.

#### **EMTALA**

There are several specific provisions we wish to call attention to under EMTALA<sup>i</sup>:

#### **Emergency Medical Condition (EMC):**

Once an individual has presented to the hospital seeking emergency care, the determination of whether an Emergency Medical Condition exists is made by the examining physician(s) or other qualified medical personnel of the hospital.

An EMC includes medical conditions with acute symptoms of sufficient severity that, in the absence of immediate medical attention, could place the health of a person (including pregnant patients) in serious jeopardy, or result in a serious impairment or dysfunction of bodily functions or any bodily organ. Further, an emergency medical condition exists if the patient may not have enough time for a safe transfer to another facility, or if the transfer might pose a threat to the safety of the person.

#### Labor

"Labor" is defined to mean the process of childbirth beginning with the latent or early phase of labor and continuing through the delivery of the placenta. A person experiencing contractions is in true labor, unless a physician, certified nurse-midwife, or other qualified medical person acting within their scope of practice as defined in hospital medical staff bylaws and State law, certifies that, after a reasonable time of observation, the person is in false labor.

#### **Medical Screening Examination**

Individuals coming to the "emergency department" must be provided a medical screening examination appropriate to the presenting signs and symptoms, as well as the capability and capacity of the hospital. Depending on the individual's presenting signs and symptoms, an appropriate medical screening exam can involve a wide spectrum of actions, ranging from a simple process involving only a brief history and physical examination to a complex process that also involves performing ancillary studies and procedures, such as (but not limited to) lumbar punctures, clinical laboratory tests, CT scans, and/or other diagnostic tests and procedures. The medical record must reflect continued monitoring according to the individual's needs until it is determined whether or not the individual has an EMC and, if they do, until they are stabilized or appropriately transferred. There should be evidence of this ongoing monitoring prior to discharge or transfer.

#### People in Labor

• Regardless of State laws, requirements, or other practice guidelines, EMTALA requires that a person in labor may be transferred only if the individual or their representative requests the transfer after informed consent or if a physician or other qualified medical personnel signs a certification at the time of transfer, with respect to the person in labor, that "the benefits of the transfer to the woman and/or the unborn child outweigh its risks." For example, if the hospital does not have staff or

<sup>&</sup>lt;sup>2</sup> State Operations Manual: Appendix V – Interpretive Guidelines – Responsibilities of Medicare Participating

Case 5:22-cv-00185-H Document 1-1 Filed 07/14/22 Page 5 of 7 PageID 25 resources to provide obstetrical services, the benefits of a transfer may outweigh the risks.

- A hospital cannot cite State law or practice as the basis for transfer. Fear of violating state law through the transfer of the patient cannot prevent the physician from effectuating the transfer nor can the physician be shielded from liability for erroneously complying with state laws that prohibit services such as abortion or transfer of a patient for an abortion when the original hospital does not have the capacity to provide such services. When a direct conflict occurs between EMTALA and a state law, EMTALA must be followed.
- Hospitals that are not capable of handling high-risk deliveries or high-risk infants often have written transfer agreements with facilities capable of handling high-risk cases. The hospital must still meet the screening, treatment, and transfer requirements.

#### **Stabilizing Treatment**

After the medical screening has been implemented and the hospital has determined that an emergency medical condition exists, the hospital must provide stabilizing treatment within its capability and capacity. Section 42 CFR 489.24(b) defines **stabilized** to mean:

"... that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility, or with respect to an "emergency medical condition" as defined in this section under paragraph (2) of that definition..."

The EMTALA statute requires that stabilizing treatment prevent material deterioration and compels hospitals and physicians to act prior to the patient's condition declining. The course of stabilizing treatment is under the purview of the physician or qualified medical personnel. If qualified medical personnel determine that the patient's condition, such as an ectopic pregnancy, requires stabilizing treatment to prevent serious jeopardy to the patient's health (including a serious impairment or dysfunction of bodily functions or any bodily organ or a threat to life), the qualified medical personnel is required by EMTALA to provide the treatment.

As indicated above, the determination of an emergency medical condition is the responsibility of the examining physician or other qualified medical personnel. Emergency medical conditions involving pregnant patients may include, but are not limited to: ectopic pregnancy, complications of pregnancy loss, or emergent hypertensive disorders, such as preeclampsia with severe features. The course of treatment necessary to stabilize such emergency medical conditions is also under the purview of the physician or other qualified medical personnel. Stabilizing treatment could include medical and/or surgical interventions (e.g., methotrexate therapy, dilation and curettage (D&C), removal of one or both fallopian tubes, anti-hypertensive therapy, etc.).

#### **Hospital's Obligation**

A hospital's EMTALA obligation ends when a physician or qualified medical person has

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- That no emergency medical condition exists (even though the underlying medical condition may persist);
- That an emergency medical condition exists and the individual is appropriately transferred to another facility; or
- That an emergency medical condition exists and the individual is stabilized or admitted to the hospital for further stabilizing treatment.

Any state that has a more restrictive definition of emergency medical condition or that has a definition that directly conflicts with any definition above is preempted by the EMTALA statute. Physicians and hospitals have an obligation to follow the EMTALA definitions, even if doing so involves providing medical stabilizing treatment that is not allowed in the state in which the hospital is located. Hospitals and physicians have an affirmative obligation to provide all necessary stabilizing treatment options to an individual with an emergency medical condition.

The EMTALA statute requires that all patients receive an appropriate medical screening, stabilizing treatment, and transfer, if necessary, irrespective of any state laws or mandates that apply to specific procedures.

A physician's professional and legal duty to provide stabilizing medical treatment to a patient who presents to the emergency department and is found to have an emergency medical condition preempts any directly conflicting state law or mandate that might otherwise prohibit such treatment. EMTALA's preemption of state law could be enforced by individual physicians in a variety of ways, potentially including as a defense to a state enforcement action, in a federal suit seeking to enjoin threatened enforcement, or, when a physician has been disciplined for refusing to transfer an individual who had not received the stabilizing care the physician determined was appropriate, under the statute's retaliation provision.

#### **Enforcement**

HHS, through its Office of the Inspector General (OIG), may impose a civil monetary penalty on a hospital (\$119, 942 for hospitals with over 100 beds, \$59,973 for hospitals under 100 beds/per violation) or physician (\$119,942/violation) pursuant to 42 CFR §1003.500 for refusing to provide either any necessary stabilizing care for an individual presenting with an emergency medical condition that requires such stabilizing treatment, or an appropriate transfer of that individual if the hospital does not have the capacity to stabilize the emergency condition. Under this same authority, HHS OIG may also exclude physicians from participation in Medicare and State health care programs. CMS may also penalize a hospital by terminating its provider agreement. Additionally, private citizens who are harmed by a physician's or hospital's failure to provide stabilizing treatment may file a civil suit against the hospital to obtain damages available under the personal injury laws of that state in which the hospital is located, in addition to recouping any equitable relief as is appropriate. 42 U.S.C. § 1395dd(d)(2)(A).

Any state actions against a physician who provides an abortion in order to stabilize an emergency medical condition in a pregnant individual presenting to the hospital would be preempted by the federal EMTALA statute due to the direct conflict with the "stabilized" provision of the statute. Moreover, EMTALA contains a whistleblower provision that prevents

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retaliation by the hospital against any hospital employee or physician who refuses to transfer a patient with an emergency medical condition that has not been stabilized by the initial hospital, such as a patient with an emergent ectopic pregnancy, or a patient with an incomplete medical abortion.

To file an EMTALA complaint, please contact the appropriate state survey agency: <a href="https://www.cms.gov/Medicare/Provider-Enrollment-and-">https://www.cms.gov/Medicare/Provider-Enrollment-and-</a>
Certification/SurveyCertificationGenInfo/ContactInformation

Individuals who believe they have been discriminated against on the basis of race, color, national origin, sex (including sexual orientation, gender identity, and pregnancy), age, disability, religion, or the exercise of conscience in programs or activities that HHS directly operates or to which HHS provides federal financial assistance, may file a complaint with the HHS Office for Civil Rights at <a href="http://www.hhs.gov/civil-rights/filing-a-complaint/complaint-process/index.html">http://www.hhs.gov/civil-rights/filing-a-complaint/complaint-process/index.html</a>. With regard to civil rights protections against national origin discrimination, hospitals covered by EMTALA must take reasonable steps to provide meaningful access to their programs and activities by persons with limited English proficiency (LEP). In most cases, hospitals must provide some form of language assistance service, such as provide an interpreter at no cost to the patient or provide important documents translated into the patient's preferred language. Hospitals may learn more about their obligations to persons with LEP by visiting the HHS *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons*.

**Contact:** Questions about this memorandum should be addressed to QSOG Hospital@cms.hhs.gov.

**Effective Date:** Immediately. This policy should be communicated to all survey and certification staff and managers immediately.

/s/

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Director, Survey & Operations Group

David R. Wright
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cc: Survey and Operations Group Management Office of Program Operations and Local Engagement (OPOLE) Centers for Clinical Standards and Quality (CCSQ)

<sup>&</sup>lt;sup>3</sup> For more information about the laws and regulations enforced by OCR, please visit <a href="https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html">https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html</a>.